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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,097	02/21/2002	Kevin J. Rozeboom	066379-9001	2833

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,097	ROZEBOOM ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *19-22,33-47 and 50-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-18,23-32,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of the Group I (claims 1-18, 23-32, 48 and 49) in Paper No. 5 is acknowledged. The traversal is on the ground(s) that several groups of inventions are not distinct inventions and that there is no burden in examining several groups of inventions. This is not found persuasive because claims are drawn to various compositions comprising different components as required by independent claims and, thus, the claimed subject matter is distinct. Moreover, the reference which would be applied to one group would not necessarily anticipates or render obvious the other groups. As to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists. Clearly different searches and issues are involved with each group. For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 19-22, 33-47 and 50-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicants timely traversed the restriction requirement in Paper No. 5 filed 6/04/2003.

Claims 1-18, 23-32, 48 and 49 are under examination in the instant office action.

Claim Objections

Claims 28 and 49 are objected to because of the following informalities:

There are some typing errors in these claims, for example: missing coma at the end.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 14-16, 18, 23, 24, 26, 29, 32 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,150,163 in the light of evidence provided by the ATCC Catalogue.

Claims are directed to an animal cell culture medium composition comprising at least one growth selected from the group consisting of insulin-like growth factor (IGF) and transforming growth factor (TGF). Some claims are further drawn to the use of TGF beta 1 or TGF beta 2 in the cell culture medium. Some claims are further drawn to the use of IGF-1. Some claims are further drawn to the use of TGF beta 1 at concentration from about 0.1 ng/L to about 10 μg/L and to the use of IGF-1 at concentration from about 0.1 ng/L to about 30 μg/L. Some claims are further drawn to incorporation of inositol or transferrin in the cell culture medium. Some claims are further drawn to incorporation of cryopreservative in the culture medium. Some claims are further drawn to incorporation of zinc in the culture medium.

US 6,150,163 discloses an animal cell culture medium composition comprising combination of growth factors TGF beta and IGF (abstract or col. 29, lines 37-39). The concentrations for growth factors are 100 ng/L or from 200 to 500 ng/L for TGF beat 1 or for

TGF beta 2 (col. 29, line 37; col. 28, lines 34-36; col.30, line 31) and 10000 ng/L for IGF-1 (col. 29, lines 37-38) what is within the claimed concentration ranges. The cell culture composition of the cited patent also comprises supplement "ITS" which includes transferrin (col. 4, lines 5-7 and col. 28, lines 34-37, col. 29, line 33). The basal culture medium in the complete defined media of the cited patent is medium HAM'S or medium DRF wherein these basal media comprise inositol and zinc (see tables 2 and 3; col. 4, line 62; col. 5, line 40 and line 64; col. 6, line 38). The cell culture composition of the cited patent also comprises cryopreservative such as, for example: serum albumin. Thus, the cited patent discloses cell culture media that comprise the same ingredients at the same concentrations as required by the presently claimed invention. The cell culture media of the cited patent is suitable for animal cells and, thus, it is physiologically acceptable and suitable for culturing various types of cells including sperm cells of various animals as intended for the composition of the present invention within the meaning of the claims.

Claims 1-11, 18, 23, 33 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Naz et al in the light of evidence provided by the ATCC Catalogue.

Claims are directed to a cell culture medium composition comprising at least one growth factor or transforming growth factor (TGF). The cell culture medium is intended for sperm cells. Some claims are further drawn to the use of TGF beta 1 at concentration from about 0.1 ng/L to about 10 μg/L in the culture medium. Some claims are further drawn to incorporation of inositol in the cell culture medium. Some claims are further drawn to incorporation of cryopreservative

in the culture medium. Some claims are further drawn to incorporation of zinc in the culture medium.

The reference by Naz et al discloses a cell culture medium for sperm cells that comprises medium Ham's F-10 (page 157, col. 1, par. 2, line 6) and growth factor TGF beta or TGF beta-1 at concentration 5-50 ng/ml or 5000-50000 ng/L (see tables 1 and 2). The regular formulation medium Ham's F10 includes inositol and zinc (see ATCC Catalogue page 518) as well as some cryoprotective agents such as, for example: amino acids (glutamic acid) or sugar (glucose). Thus, the composition of the cited reference comprises the same ingredients at the same concentration as the claimed composition. Therefore, the cited reference anticipates the claimed invention.

Claims 1-9, 14, 15, 32 and 48 are rejected under 35 U.S.C. 102(b) as being by Lackey et al.

Claims are directed to a cell culture medium composition comprising at least one growth factor or with insulin like growth factor (IGF-1). The cell culture medium is intended for sperm cells. Some claims are further drawn to incorporation of inositol in the cell culture medium. Some claims are further drawn to incorporation of cryopreservative in the culture medium. Some claims are further drawn to incorporation of zinc in the culture medium.

The reference by Lackey et al discloses a cell culture medium for sperm cells that comprises a balanced salt buffer MTM or Tyrodes' medium and growth factor IGF-1 at concentration 100 ng/mL (abstract page 117). The composition of the cited reference also comprises cryoprotective agent such as, for example: serum albumin BSA. Thus, the

composition of the cited reference comprises the same ingredients as the claimed composition. Therefore, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18, 23-32, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,150,163.

Claims 1-12, 14-16, 18, 23, 24, 26, 29, 32 and 48 as explained above. Some claims are further drawn to incorporation of all three growth factors TGF beta 1, TGF beta 2 and IGF-1 into the cell culture medium (claims 13, 17 and 49). Some claims are further drawn to the use of particular concentrations of growth factors TGF beta 1, TGF beta 2 and IGF-1 in the animal cell culture media.

The cited patent US 6,150,163 is relied upon as explained above. Although the complete defined cell culture medium of the cited patent US 6,150,163 includes combination of two growth factors IGF-1 and either TGF beta 1 or TGF beta 2, the cited patent teaches that TGF beta 1 and TGF beta 2 are equivalents and that they have similar properties and produce the same effects in animal cell culture medium (example 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine all three growth factors including IGF-1, TGF beta 1

and TGF beta 2 in an animal cell culture medium with a reasonable expectation of success in culturing animal cells because the prior art teaches combination of IFG-1 and TGF beta in one culture medium composition wherein TGF beta 1 and beta 2 are equivalents in the animal cell culture medium as taught and suggested by the prior art. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Further, it is considered to be within the purview of ordinary skill practitioner to adjust concentrations of particular growth factors and/or other ingredients with regard to a particular type of cells or a type of animals for the expected benefit in maximizing animal cell viability and/or optimizing animal cell survival, grow, proliferation, differentiation and/or preservation.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Claims 1-18, 23-32, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over the reference by Naz et al. and the reference by Lackey et al. taken with ATCC Catalogue, US patent 6,140,121 [IDS reference AD], US 6,150,163 and reference by Nocera et al.

Claims are directed to a cell culture medium composition comprising at least one growth selected from the group consisting of insulin-like growth factor (IGF) or transforming growth factor (TGF). The cell culture medium is intended for animal sperm cells. Some claims are further drawn to the use of TGF beta 1 or TGF beta 2 in the cell culture medium. Some claims are further drawn to the use of IGF-1. Some claims are further drawn to combination of two growth factors TGF beta 1 and TGF beta 2 or to combination of three growth factors TGF beta 1, TGF beta 2 and IGF-1 in the culture medium. Some claims are further drawn to the use of TGF beta 1 at concentration from about 0.1 ng/L to about 10 μg/L in the culture medium, to the use of TGF beta 2 concentration from about 0.1 ng/L to about 200 ng/L in the cell culture medium and to the use of IGF-1 at concentration from about 0.1 ng/L to about 30 μg/L in the cell culture medium. Some claims are further drawn to incorporation of inositol or transferrin or fructose in the cell culture medium. Some claims are further drawn to incorporation of cryopreservative in the culture medium. Some claims are further drawn to incorporation of zinc in the culture medium.

The references by Naz et al. and by Lackey et al. are relied upon as explained above for the disclosure of animal sperm cell culture media with at least one growth factor TGF beta or IGF-1 in view of the disclosure by the ATCC Catalogue which provides evidence related to the presence of zinc and inositol in the regular basal animal cell culture media. In addition, US 6,140,121 is relied upon to demonstrate that animal sperm cell culture media comprise basal media or balanced salt solutions, growth factors and other sperm stimulants, supplements and additives (col. 15, line 1 and lines 53-67) suitable for sperm cells of various animal including humans, avians or exotic species (col. 4, lines 50-52).

The compositions of both cited references by Naz et al. and by Lackey et al. comprise various cryoprotective agents as explained above. But they are missing disclosure related to the use of fructose as cryoprotective agent. However, the cited US 6,140,121 teaches the use of fructose in compositions intended for freezing animal sperm cells, for example: see col. 26, lines 44-49) as well as other cryoprotective agents including serum albumin, amino acids and sugars (see paragraph bridging col.16 and col. 17) that are disclosed by references by Naz et al. and by Lackey et al.

The cited references by Naz et al. and by Lackey et al are silent with regard to trasferrin in basal culture media. However, the cited patent US 6,150,163 teaches incorporation of transferrin supplement into basal animal cell culture media with growth factor(s) (table 1).

Both cited references by Naz et al. and by Lackey et al. disclose concentrations of at least one growth factor in sperm culture media that are within the presently claimed ranges. In particular, the reference by Naz et al. teaches incorporation of growth factor TGF beta 1 into sperm cell culture medium but it is silent with regard to growth factor IGF. However, the reference by Lackey et al teaches incorporation of IGF-1 into animal sperm cell culture medium. Further, the reference by Lackey et al also teaches that growth factors including IGF are within animal seminal plasma or a natural environment for animal sperm cells. In addition, the reference by Nocera et al. teaches that other growth factors including TGF beta 1 and TGF beta 2 are also within animal seminal plasma.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine growth factors including IGF-1, TGF beta 1 and TGF beta 2 in an animal sperm cell culture medium with a reasonable expectation of success in

providing a physiologically suitable medium for sperm cells of various animals because the physiologically suitable conditions provided by seminal plasma include growth factors that are presently claimed and because the prior art teaches incorporation of growth factors TGF beta and IGF into artificial cell culture media intended for sperm cells. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Further, it is considered to be within the purview of ordinary skill practitioner to adjust concentrations of particular growth factors and/or other ingredients with regard to a particular application intended for sperm cells for the expected benefit in maximizing sperm viability and/or optimizing sperm survival, preservation and/or fertility.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on 9.30 am - 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

August 19, 2003

VERA AFREMOVA

PATENT EXAMINER

V. Afremova